K073014

510(K) SUMMARY

Submitted By

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JAN 25 2008

Contact: Evelyn Lopez
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Device Name

Trade or Proprietary Name: INFINITI 2C9 & VKORC1 Multiplex Assay for Warfarin

Common or Usual Name: 2C9 and VKORC1 Drug Metabolizing Enzyme Genotyping System

Regulations and Product Codes

Regulations: 21CFR§862.3360 Drug Metabolizing Enzyme Genotyping Systems
21CFR§864.7750 Prothrombin Time Test
21CFR§862.2570 Instrumentation for Clinical Multiplex Test Systems

Product Codes: ODW Cytochrome P450 2C9 (CYP450 2C9) Drug Metabolizing Enzyme Genotyping System
ODV Vitamin K epoxide reductase complex subunit 1 (VKORC1) Genotyping System
NSU Instrumentation for Clinical Multiplex Test Systems

Predicate Device

(a) AmpliChip CYP450 Test for CYP2C19
(b) INFINITI System Assay for Factor II & Factor V

Device Description

The INFINITI 2C9 & VKORC1 Multiplex Assay for Warfarin is an *in vitro* diagnostic device which utilizes proprietary film-based microarray technology combined with process automation, reagent management, and software technology for the detection and genotyping of the 2C9*2, 2C9*3, and VKORC1 3673 (-1639) mutations from EDTA-anticoagulated whole blood samples.

The INFINITI 2C9 & VKORC1 Multiplex Assay for Warfarin is comprised of the BioFilmChip™ Microarray, the Intellipac Reagent Module and the PCR Amplification Mix. The INFINITI 2C9 & VKORC1 Multiplex Assay for Warfarin should be run using the AutoGenomics INFINITI Analyzer.

The BioFilmChip Microarray consists of a polyester film coated with proprietary multi-layer components designed for DNA analysis. The layers have been designed to provide a versatile surface to enhance test performance. There can be up to 240 spots per microarray with each spot representing a different allele. The microarrays are designed to be assay specific.

The Intellipac Reagent Module contains up to eight reservoirs that house the test reagents and has an integrated memory chip. Information on the reagent such as lot number, expiration date and volume usage, are archived in the memory.

The PCR Amplification Mix consists of the reagents needed for the PCR amplification step of the assay.

The INFINITI 2C9 & VKORC1 Multiplex Assay for Warfarin is based on the following processes:

(a) DNA extraction
(b) PCR amplification of purified DNA from human genomic DNA
(c) Labeling of the amplified product (allele specific primer extension)
(d) Hybridization of the labeled amplified product to a microarray by signature Tag/Capture probe hybridization under isothermal conditions.
(e) Scanning of the microarray
(f) Signal detection and analysis [determination of the 2C9*2, 2C9*3 and VKORC1 3673 (-1639) genotypes]

Steps (c) through (f) are automated by the INFINITI Analyzer.

The INFINITI Analyzer automates the 2C9 and VKORC1 assays and integrates all the discrete processes of sample (PCR amplicon) handling, reagent management, hybridization, detection, and results analysis. The assays are processed automatically and read by the built-in confocal microscope. Results are analyzed and presented as genotype calls.

Intended Use

The INFINITI 2C9 & VKORC1 Multiplex Assay for Warfarin is an *in vitro* diagnostic test for the detection and genotyping of the *2 and *3 CYP4502C9 genetic variants and the VKORC1 3673 (-1639) intronic variant in genomic deoxyribonucleic acid (DNA) obtained from EDTA-anticoagulated whole blood samples. The INFINITI 2C9 & VKORC1 Multiplex Assay for Warfarin is a qualitative assay for use in clinical laboratories upon prescription by the attending physician.

Indication for Use

The INFINITI 2C9 & VKORC1 Multiplex Assay for Warfarin is indicated for use to identify individuals at risk for sensitivity to warfarin.

Substantial Equivalence

Tables 1a and 1b provide a comparison of the technological characteristics of the INFINTI 2C9 & VKORC1 Multiplex Assay for Warfarin to those of the predicate devices

- AmpliChip CYP450 Test for CYP2C19 (k043576)
- INFINITI System Assay for Factor II & Factor V (k060564)

Table 1a

Characteristics	Predicate AmpliChip CYP450 Test for CYP2C19	Subject Device INFINITI 2C9 & VKORC1 Multiplex Assay for Warfarin
Similarities		
DNA sequence	Detects specific DNA sequences through recognition of DNA targets	Same
Technology	Microarray-based genotyping test for simultaneous detection (multiplex system) of DNA sequences	Same
Specimen Type	Purified DNA from human blood samples	Same
Reaction Conditions	• Utilizes thermal cycling • Utilizes target DNA amplification	Same
Assay Results	• Assay signal results are interpreted by a software program • Assay results are provided as genotype calls reported to the end user in a report format	Same
Differences		
Gene	CYP2D6 and CYP2C19	CYP2C9 and VKORC1
Microarray substrate	Reactions occur on a single glass slide	Reactions occur on a single biofilm microarray chip
Number of alleles	2	3

Table 1b

Characteristics	Predicate INFINITI System Assay for Factor II & Factor V	Subject Device INFINITI 2C9 & VKORC1 Multiplex Assay for Warfarin
Similarities		
DNA sequence	Detects specific DNA sequences through recognition of DNA targets	Same
Technology	Microarray-based genotyping test for simultaneous detection (multiplex system) of DNA sequences	Same
Specimen Type	Purified DNA from human blood samples	Same
Reaction Conditions	• Utilizes thermal cycling • Utilizes target DNA amplification	Same
Microarray substrate	Reactions occur on a single biofilm microarray chip	Same
Assay Results	• Assay signal results are interpreted by a software program • Assay results are provided as genotype calls reported to the end user in a report format	Same
Differences		
Gene	Factor II and Factor V	CYP2C9 and VKORC1
Number of alleles	2	3

Performance The following are performance characteristics of the INFINITI 2C9 & VKORC1 Multiplex Assay for Warfarin:

Analytical Specificity

Studies related to specificity were conducted during assay development. PCR primer specificity was determined by amplicon size on a gel and sequencing the amplicon. ASP primer specificity was determined by the correct calls made by the assay using known genomic samples. Capture probe specificity was determined by hybridizing different oligos and demonstrating that correct oligo hybridizes to the known spot.

Limit of Detection (analytical sensitivity)

Serial dilutions (200, 100, 50, 25, 10, 1, 0.1ng DNA) were prepared from a known purified DNA sample. Each serial dilution was assayed three times using the INFINITI 2C9 & VKORC1 Multiplex Assay for Warfarin. The study established the minimum DNA concentration for the INFINITI System Assay for 2C9-VKORC1 to be 1ng DNA. The recommended DNA concentration for the INFINITI 2C9 & VKORC1 Multiplex Assay for Warfarin is 25ng/µl. The assay requires 2µl of DNA sample or the equivalent of 50ng per test.

In addition, the same study demonstrated that DNA concentrations of 100ng and 200ng, which were in excess of the recommended concentration (50ng), did not interfere with the INFINITI 2C9 & VKORC1 Multiplex Assay for Warfarin. The following table provides a summary of the results of the study.

Limit of Detection

Sample				Run 1				Run 2				Run 3			
	Genotype			Genotype Calls				Genotype Calls				Genotype Calls			
ng DNA	2C9		VKORC1 3673 (-1639)	2C9		VKORC1 3673 (-1639)	Result	2C9		VKORC1 3673 (-1639)	Result	2C9		VKORC1 3673 (-1639)	Result
	*2	*3		*2	*3			*2	*3			*2	*3		
200	W	W	H	W	W	H	Pass	W	W	H	Pass	W	W	H	Pass
100	W	W	H	W	W	H	Pass	W	W	H	Pass	W	W	H	Pass
50	W	W	H	W	W	H	Pass	W	W	H	Pass	W	W	H	Pass
25	W	W	H	W	W	H	Pass	W	W	H	Pass	W	W	H	Pass
10	W	W	H	W	W	H	Pass	W	W	H	Pass	W	W	H	Pass
1	W	W	H	W	W	H	Pass	W	W	H	Pass	W	W	H	Pass
0.1	W	W	H	No call	W	H	Fail	W	W	H	Pass	No call	W	H	Fail

Percent Agreement vs. Bi-directional Sequencing

The INFINITI 2C9 & VKORC1 Multiplex Assay for Warfarin was compared to bi-directional sequencing as the comparator method. Three sites were used for the comparison studies. Each site tested its own patient samples with the INFINITI 2C9-VKORC1 Multiplex Assay for Warfarin. All samples used in the comparison studies at the three sites were from patients using or have used warfarin. Patient samples were de-identified to protect patient's identity. Each site performed the DNA extraction using a different extraction method. The results of the comparison studies demonstrated

98.0% agreement for 2C9*2 as compared with bi-directional sequencing on 1st run
97.3% agreement for 2C9*3 as compared with bi-directional sequencing on 1st run
98.0% agreement for VKORC1 3673 (-1639) as compared with bi-directional sequencing on 1st run

The results of the comparison studies are summarized in Table 2a and Table 2b.

Table 2a Agreement between INFINITI 2C9 & VKORC1 Multiplex Assay for Warfarin and Bi-Directional DNA Sequencing

Genotype[a]	Number Tested	Replicates per Sample	Number of Correct Genotype Calls[b]	Number of Incorrect Calls	No Calls	Agreement	95% One-Sided Confidence Lower Limit
2C9*2 *1/*2	35	1	34	0	1	97.1%	88.82%
2C9*2 *2/*2	2	1	2	0	0	100.0%	50%[d]
2C9*2 *1/*1	113	1	111	0	2	98.2%	94.91%
Total for 2C9*2	150	1	147	0	3	98.0%	95.09%
2C9*3 *1/*3	19	1	19	0	0	100.0%	80.45%
2C9*3 *3/*3	1	1	1	0	0	100.0%	0%[d]
2C9*3 *1/*1	130	1	126	1[c]	3	96.9%	94.30%
Total for 2C9*3	150	1	146	1	3	97.3%	94.09%
VKORC1 3673 (-1639) GA	63	1	62	0	1	98.4%	93.74%
VKORC1 3673(-1639) AA	27	1	25	0	2	92.6%	79.01%
VKORC1 3673 (-1639) GG	60	1	60	0	0	100.0%	98.33%
Total for VKORC1 3673 (-1639)	150	1	147	0	3	98.0%	95.09%
Total for Assay	450	1	440	1	9	97.8%	96.86%

[a] Genotype determined through bi-directional DNA sequencing

[b] Calls produced on first run

[c] Initial INFINITI results (*1/*1 for 2C9*2, ***1/*3 for 2C9*3*** and GG for VKORC1 3673) did not match bi-directional sequence results (*1/*1 for 2C9*2, ***1/*1 for 2C9*3*** and GG for VKORC1 3673). The same INFINITI results were obtained on repeat run. Reason unknown.

d For sample sizes 1 and 2, and 100% agreement, SE(p2-p1)=0. Pure sample size correction for sample size 2 is 50% and for sample size 1 is 100%, therefore, One-Sided Confidence Lower Limits are 50% (n=2) and 0% (n=1).

Table 2b Agreement between INFINITI 2C9 & VKORC1 Multiplex Assay for Warfarin and Bi-Directional DNA Sequencing (by Sample Type)

Sample Description Genotype[a]			# Samples Tested	First Time Run					Final Result[d]				
2C9		VKORC1 3673 (-1639)		Samples with Genotype Calls made by INFINITI[b]	Samples with Correct Calls[c]	Samples with No Calls	Samples with Incorrect Calls	Correct Call Rate[e] (%)	Samples with Genotype Calls made by INFINITI[b]	Samples with Correct Calls[c]	Samples with No Calls	Samples with Incorrect Calls	Correct Call Rate[e] (%)
*2	*3												
*1/*1	*1/*1	AA	20	18	18	2	0	90.0	20	20	0	0	100
*1/*1	*1/*1	GA	34	34	34	0	0	100	34	34	0	0	100
*1/*1	*1/*1	GG	43	43	42	0	1[f]	97.7	43	42	0	1	97.7 (42/43)
*1/*2	*1/*1	AA	4	4	4	0	0	100	4	4	0	0	100
*1/*2	*1/*1	GA	15	14	14	1	0	93.3	15	15	0	0	100
*1/*2	*1/*1	GG	12	12	12	0	0	100	12	12	0	0	100
*1/*1	*1/*3	AA	2	2	2	0	0	100	2	2	0	0	100
*1/*1	*1/*3	GA	10	10	10	0	0	100	10	10	0	0	100
*1/*1	*1/*3	GG	3	3	3	0	0	100	3	3	0	0	100
*2/*2	*1/*1	GA	1	1	1	0	0	100	1	1	0	0	100
*2/*2	*1/*1	GG	1	1	1	0	0	100	1	1	0	0	100
*1/*2	*1/*3	AA	1	1	1	0	0	100	1	1	0	0	100
*1/*2	*1/*3	GA	2	2	2	0	0	100	2	2	0	0	100
*1/*2	*1/*3	GG	1	1	1	0	0	100	1	1	0	0	100
*1/*1	*3/*3	GA	1	1	1	0	0	100	1	1	0	0	100
Total			150	147	146	3	1	97.3	150	149	0	1	99.3 (149/150)

a Genotype determined through bi-directional DNA sequencing

b Excludes samples with indeterminate/no calls

c A sample with correct call indicates a correct call at all three loci. One incorrect or no call at one out of the three loci for the sample is considered an incorrect call for the whole sample

d Final results reflect one time repeat of samples with indeterminate (no) calls

e Correct call rate = # samples with correct calls/# samples tested

f Initial INFINITI results (*1/*1 for 2C9*2, ***1/*3 for 2C9*3** and GG for VKORC1 3673) did not match bi-directional sequence results (*1/*1 for 2C9*2, ***1/*1 for 2C9*3** and GG for VKORC1 3673). The same INFINITI results were obtained on repeat run. Reason unknown.

Assay Inter-Laboratory Reproducibility

A three-site study was conducted to demonstrate the reproducibility of the INFINITI 2C9 & VKORC1 Multiplex Assay for Warfarin. The study involved three identical lots of the INFINITI 2C9 & VKORC1 Multiplex Assay for Warfarin. The sites ran identical samples comprised of seven genomic DNA samples and five whole blood samples. The sites were blinded to sample identity. Each site used a different DNA extraction method. At each site, each sample was run in duplicate per day/operator for six days. Three operators were required for each site. Results of the inter-laboratory reproducibility study are summarized in Tables 3a and 3b.

Table 3a Inter-Laboratory Reproducibility of the INFINITI 2C9 & VKORC1 Multiplex Assay for Warfarin by Genotype calls

Genotype	Samples Tested	Tests Per Site	Site	Genotype Calls	First Time Run					Final Result*				
					Correct Calls	Incorrect Calls	No Calls	% Correct Calls	95% One-Sided Confidence Lower Limit	Correct Calls	Incorrect Calls	No Calls	% Correct Calls	95% One-Sided Confidence Lower Limit
2C9*2 *1/*2	3	36	1	36	36	0	0	100		36	0	0	100	
			2	36	34	0	2[b]	94.4		36	0	0	100	
			3	36	36	0	0	100		36	0	0	100	
			total	108	106	0	2	98.15	95.14%	108	0	0	100	99.53%
2C9*2 *2/*2	1	12	1	12	12	0	0	100		12	0	0	100	
			2	12	11	0	1[b]	91.7		12	0	0	100	
			3	12	12	0	0	100		12	0	0	100	
			total	36	35	0	1	97.22	90.47%	36	0	0	100	98.61%
2C9*2 *1/*1	8	96	1	96	95	0	1[a]	99.0		96	0	0	100	
			2	96	96	0	0	100		96	0	0	100	
			3	96	96	0	0	100		96	0	0	100	
			total	288	287	0	1	99..65	99.13	288	0	0	100	99.83
Total for 2C9*2				432	428	0	4	99.07	98.06%	432	0	0	100	99.88
2C9*3 *1/*3	2	24	1	24	24	0	0	100		24	0	0	100	
			2	24	22	0	2[b]	91.7		24	0	0	100	
			3	24	24	0	0	100		24	0	0	100	
			total	72	70	0	2	97.22	92.73%	72	0	0	100	99.30%
2C9*3 *3/*3	2	24	1	24	24	0	0	100		24	0	0	100	
			2	24	24	0	0	100		24	0	0	100	
			3	24	23	0	1[c]	95.8		24	0	0	100	
			total	72	71	0	1	98.61	95.21%	72	0	0	100	99.30%
2C9*3 *1/*1	8	96	1	96	95	0	1[a]	99.0		96	0	0	100	
			2	96	95	0	1[b]	99.0		96	0	0	100	
			3	96	96	0	0	100		96	0	0	100	
			total	288	286	0	2	99.31	98.17%	288	0	0	100	99.83%
Total for 2C9*2				432	427	0	5	98.84	97.72%	432	0	0	100	99.88%
VKORC1 3673 (-1639) GA	5	60	1	60	60	0	0	100		60	0	0	100	
			2	60	59	0	1[b]	98.3		60	0	0	100	
			3	60	60	0	0	100		60	0	0	100	
			total	180	179	0	1	99.44	98.08%	180	0	0	100	99.72%
VKORC1 3673 (-1639) AA	2	24	1	24	24	0	0	100		24	0	0	100	
			2	24	22	0	2[b]	91.7		24	0	0	100	
			3	24	24	0	0	100		24	0	0	100	
			total	72	70	0	2	97.22	92.73	72	0	0	100	99.30%
VKORC1 3673 (-1639) GG	5	60	1	60	59	0	1[a]	98.3		60	0	0	100	
			2	60	60	0	0	100		60	0	0	100	
			3	60	60	0	0	100		60	0	0	100	
			total	180	179	0	1	99.44	98.08%	180	0	0	100	99.72%
Total for VKORC1 3673 (-1639)				432	428	0	4	99.07	98.06%	432	0	0	100	99.88%

Genotype	Samples Tested	Tests Per Site	Site	Genotype Calls	First Time Run					Final Result*				
					Correct Calls	Incorrect Calls	No Calls	% Correct Calls	95% One-Sided Confidence Lower Limit	Correct Calls	Incorrect Calls	No Calls	% Correct Calls	95% One-Sided Confidence Lower Limit
Total per Site			1	432	429	0	3	99.3	98.41%	432	0	0	100	99.88%
			2	432	423	0	9	97.9	96.45%	432	0	0	100	99.88%
			3	432	431	0	1	99.8	99.31%	432	0	0	100	99.88%
Total for Assay				1296	1283	0	13	98.99	98.42%	1296	0	0	100	99.96%

* Results after one repeat of samples

a Site 1: no results - no tips for one sample; repeat OK

b Site 2: no results - tip sensor did not sense liquid due low volume of wash buffer on one sample; correct test result achieved on second test.
no calls on two samples - reason unknown; correct test result achieved on second test

c Site 3: one sample had no call; correct test result achieved on second test

Table 3b Reproducibility Study Results by Sample Type

Sample ID	Genotype			# Samples Tested	First Time Run					Final Result[c]				
	2C9		VKORC1 3673 (-16390		Samples with Genotype Calls made by INFINITI[a]	Samples with Correct Calls[b]	Samples with No Calls	Samples with Incorrect Calls	Correct Call Rate[d] (%)	Samples with Genotype Calls made by INFINITI[a]	Samples with Correct Calls[b]	Samples with No Calls	Samples with Incorrect Calls	Correct Call Rate[d] (%)
	*2	*3												
1	*1/*2	*1/*3	AA	36	34	34	2	0	94.4	36	36	0	0	100
2	*1/*1	*1/*1	GG	36	36	36	0	0	100	36	36	0	0	100
3	*2/*2	*1/*1	GA	36	35	35	1	0	97.2	36	36	0	0	100
4	*1/*1	*3/*3	GA	36	35	35	1	0	97.2	36	36	0	0	100
5	*1/*2	*1/*1	GG	36	36	36	0	0	100	36	36	0	0	100
6	*1/*1	*1/*1	GG	36	36	36	0	0	100	36	36	0	0	100
7	*1/*1	*1/*1	GG	36	36	36	0	0	100	36	36	0	0	100
8	*1/*1	*1/*3	GA	36	36	36	0	0	100	36	36	0	0	100
9	*1/*1	*1/*1	**GG**	36	35	35	1	0	97.2	36	36	0	0	100
10	*1/*1	*3/*3	GA	36	36	36	0	0	100	36	36	0	0	100
11	*1/*2	*1/*1	GA	36	36	36	0	0	100	36	36	0	0	100
12	*1/*1	*1/*1	AA	36	36	36	0	0	100	36	36	0	0	100
Total				432	427	427	5	0	98.8	432	432	0	0	100

a Excludes samples with indeterminate/no calls

b A sample with correct call indicates a correct call at all three loci. One incorrect or no call at one out of the three loci for the sample is considered an incorrect call for the whole sample

c Final results reflect one time repeat of samples with indeterminate (no) calls

d Correct call rate = # samples with correct calls/# samples tested (excludes samples with indeterminate/no calls)

Drug Interference
Evaluation of potential interference from bilirubin, cholesterol, and heparin demonstrated that presence of these compounds in concentrations of 8mg/dl bilirubin, 70mg/dl cholesterol and 133v/dl heparin does not interfere with the INFINITI 2C9 & VKORC1 Multiplex Assay.

Sample Carry-Over
No sample carry-over was detected when 300ng of a positive sample was followed by 10ng of a second positive sample, and when 300ng of a positive sample was followed by a "No Template Control" or water. All genotype calls were 100% correct.

Assay Interference
Running the INFINITI 2C9 & VKORC1 Multiplex Assay for Warfarin and the INFINITI Assay for Factor II & Factor V on the same instrument did not affect the results of the assays, i.e., the INFINITI 2C9 & VKORC1 Multiplex Assay for Warfarin did not affect the results of the INFINITI Assay for Factor II & Factor V, and vise versa.

Reagent Stability

BioFilmChip Microaray:	12 months at RT (15-30°C)
Intellipac Reagent:	12 months Refrigerated (2-8°C)
Amplification Mix:	12 months Frozen (-10°C)

Conclusion The above pre-clinical and clinical data support the safety and effectiveness of the INFINITI 2C9 & VKORC1 Multiplex Assay for Warfarin.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 2 3 2008

Autogenomics, Inc
Ms. Evelyn Lopez
2251 Rutherford Road
Carlsbad, CA 92008

Re: k073014
Trade/Device Name: INFINITI 2C9 & VKORC1 Multiplex Assay for Warfarin
Regulation Number: 21 CFR 862.3360
Regulation Name: Drug metabolizing enzyme genotyping system
Regulatory Class: Class II
Product Code: ODW, ODV, NSU
Dated: October 23, 2007
Received: October 29, 2007

Dear Ms. Lopez:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k073014

Device Name: INFINITI 2C9 &VKORC1 Multiplex Assay for Warfarin

Indications For Use: The INFINITI 2C9 & VKORC1 Multiplex Assay for Warfarin is an *in vitro* diagnostic test for the detection and genotyping of the *2 and *3 CYP4502C9 genetic variants and the VKORC1 3673 (-1639) intronic variant in genomic deoxyribonucleic acid (DNA) obtained from EDTA-anticoagulated whole blood samples. The INFINITI 2C9 & VKORC1 Multiplex Assay for Warfarin is a qualitative assay for use in clinical laboratories upon prescription by the attending physician.

The INFINITI 2C9 & VKORC1 Multiplex Assay for Warfarin is indicated for use to identify individuals at risk for sensitivity to warfarin.

Prescription Use __X____ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) k073014